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Toward an International Standard of Scientific Inquiry

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TOWARD AN INTERNATIONAL STANDARD OF SCIENTIFIC INQUIRY†

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I. HUMAN RIGHTS AND THE NEW BIOTECHNOLOGY

UNTIL QUITE RECENTLY, the pervasive attitude among sophisticated observers in Australia, Europe and America has been one of support for scientific inquiry and discovery. It was believed that this progressive action was not only of overwhelming benefit to society, but an essential attribute of human achievement and progress in the brave new world.[1] Subsequent agonizing reflections on the horrors of the World Wars and the all too frequent limited conflicts since 1945, together sometimes with overly emotional concerns regarding the full potential for nuclear, bacteriological and chemical warfare and its very real potential for annihilating mankind, have witnessed a new and increasingly pessimistic temperament concerning scientific advancement. Indeed, it has been recognized that "not all science is good for humanity."[2]

The importance of human rights and its need to be recognized in the era of the "New Biology" was underscored by initial efforts at the United Nations in the 1970's.[3] But before that activity, the 1948 Universal Declaration of Human Rights guarantees of "human dig-

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1. Mr. Justice Michael D. Kirby, *Human Rights - The Challenge of the New Technology*, 60 AUSTRALIAN L. J. 170 (Mar. 1986). *See* Beth Gaze & Pascal Kasimba, *Embryo Experimentation: The Path and Problems of Legislation in Victoria*, in EMBRYO EXPERIMENTATION 202 (Peter Singer et al. eds., 1990) for a comparative analysis of the laws on embryo experimentation in the state of Victoria, Australia, one of the forerunners in the field, as well as other countries). Gaze & Kasimba, *supra*, at 227-29. *See also* DIETER GIESEN, INTERNATIONAL MEDICAL MALPRACTICE LAW: A COMPARATIVE LAW STUDY OF CIVIL LIABILITY ARISING FROM MEDICAL CARE 750 (1988).

2. Kirby, *supra* note 1, at 171.

3. *See id.* at 174. *See also* RICHARD B. LILLICH & FRANK C. NEWMAN, INTERNATIONAL HUMAN RIGHTS: PROBLEMS OF LAW AND POLICY (1979); Sheila Jasanoff, *Biology and the Bill of Rights: Can Science Reframe the Constitution?*, 13 AM. J. L. & MED. 249

nity" written in Articles 1, 5, 6 and 29(1)[4] established eloquent reminders of the need for the advances of biotechnology and genetic engineering to be tied to a basic understanding of, and respect for, fundamental human rights.[5]

A new human rights debate needs to emerge among not only the legal community, but also among the scientists and technocrats; a debate that would reconsider the extent to which both the traditional and the re-defined rights of humanity are challenged or complemented by the plethora of medical, legal, scientific and technological considerations of today's brave new world. Mr. Justice Michael D. Kirby of Australia succinctly summarized the issue: "If lawyers are to continue to play a relevant part in the human rights debate of the future, they must become more aware of scientific and technological advances. Otherwise, they will increasingly lack understanding of the questions to be asked, let alone the answers to be given."[6]

Law needs to direct an agenda for social change and changing social needs rather than simply responding or reacting to change. Indeed, former Chief Justice Warren E. Burger has observed, "The law does not search out as do science and medicine; it reacts to social needs and demands."[7] Law, science and medicine must become partners. They must assure society today and tomorrow, that all citizens have an equal opportunity to achieve their maximum potential within the economic marketplace, have their physical suf-

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(1987). The author delineates nine major policy areas under which seventeen situations may arise that create constitutional controversies over the new biology. *Id* at 260-61.

4. G.A. Res. 217A (III), U.N. DOC A/810 at 71 (1948).

5. Kirby, *supra* note 1, at 179. Mr. Justice Kirby has cautioned that the increasing knowledge of human fertility and its varied and mechanical applications draw new attention to other human rights guarantees.

> [Specifically] [c]an Art. 16(1) of the Universal Declaration, with its guarantee that men and women of full age have a right to marry and 'to found a family' provide support for a claim to *in vitro* fertilization, embryo transplantation, artificial insemination, surrogate parenting and womb leasing, transplantation and the like? Is the guarantee of special care and assistance for motherhood and childhood in Art. 25(2) relevant to the new procedures available to overcome infertility? Is the guarantee of adequate health and medical care in Art. 25(1) the basis for a claim of access without limitation to these new techniques?

Id. See generally George P. Smith, II, *The Razor's Edge of Human Bonding: Artificial Fathers and Surrogate Mothers*, 5 W. NEW ENG. L. REV. 639 (1983); George P. Smith, II, *The Perils and Peregrinations of Surrogate Mothers*, 1 INT'L J. MED & LAW 325 (1982); George P. Smith. II, *Through a Test Tube Darkly: Artificial Insemination and The Law*, 67 MICH. L. REV. 127 (1968).

6. *Supra* note 1, at 181.

7. Justice Warren E. Burger, *Reflections on Law and Experimental Medicine, in* 1 ETHICAL, LEGAL AND SOCIAL CHALLENGES TO A BRAVE NEW WORLD 211, 211 (George P. Smith, II ed., 1982).

fering minimized and spiritual tranquility assured.[8]

The late Professor Thomas Emerson, a great civil libertarian, cautioned in 1976 that one of the hard problems of the First Amendment would soon be acknowledged as the extent to which the state could recognize scientific research.[9] As he observed sagely, "It is hard to predict where these issues will lead."[10] This essay will explore the pathway where these issues are leading in contemporary society.

Roots of the Modern Conflict

Long before Professor Emerson, Chief Justice Burger and Justice Kirby crystallized their ideas and their predictions, the epic struggle of Galileo was played out and, as such, gave new direction to how scientific freedom of expression would be allowed in 17th century Catholic theology.[11]

Galileo was censured by Pope Urban VIII in 1633 for averring Copernicanism - the theory that put the sun at the center of the solar system. Summoned to Rome to defend his book written the previous year, DIALOGUE CONCERNING THE TWO CHIEF WORLD SYSTEMS, Galileo failed to sustain his case for free and unfettered scientific inquiry. The views of Copernicus had been censured by Rome in 1616 (even though he actually died in 1543) and, in that same year, Galileo had been warned to cease his study and advocacy of the Copernican theory. Originally condemned to life imprisonment for his views, Galileo's sentence was commuted by Urban VIII to life-long house arrest thus enabling him to return to Florence.[12]

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8. *See generally* SIR ZELMAN COWEN, REFLECTIONS ON MEDICINE, BIOTECHNOLOGY AND THE LAW (1986). *See also* Sidney A. Shapiro, *Biotechnology and The Design of Regulation*, 17 ECOLOGY L.Q. 1 (1990); Hilaire Barnett, *Biotechnology - Can the Law Cope?*, 15 ANGLO-AM. L. REV. 149 (1986); Michael H. Shapiro, *Introduction to the Issue: Some Dilemmas of Biotechnological Research*, 51 S. CAL. L. REV. 987 (1987).

9. Thomas I. Emerson, *Colonial Intentions and Current Realities of the First Amendment*, 124 U. PA. L. REV. 737 (1977). *See also* Loren R. Graham, *Concerns About Science and Attempts to Regulate Inquiry*, DAEDALUS, Spring 1978, at 1.

10. Emerson, *supra* note 9, at 746-47.

11. *See* PIETRO REDONDI, GALILEO: HERETIC (1987).

12. *Id.* It has been suggested recently that Galileo's difficulty was not with his astronomy but his physics because 17th century Roman Catholic theology could more easily tolerate and live with the Copernican system, termed heliocentnism, than with a view of physics whose atomism seemed to challenge the Eucharistic dogma that taught at Communion that bread and wine were, *ipso facto*, transubstantiated into Christ's body and blood. *Id. See also* MICHAEL SEGRE, IN THE WAKE OF GALILEO 27 (1991) (Editor's note: this Article was written and edited prior to the October 31, 1992 pardon of Galileo. For a discussion of this

Galileo's legacy is his animation of a movement designed to advance and, indeed, promote freedom of scientific expression. More specifically as to his own case, Galileo fought against the intellectual tyranny of what was termed Aristotelian scholasticism and campaigned for the advancement of a new scientific language that, in turn, would advance a basic right of research and free intellectual discourse against what were prevarications of institutional culture.[13]

II. OPPORTUNITIES FOR THE NEW BIOLOGY IN AMERICA

Modern scientific work is less a basic expression of the "ancient aristocratic ethos of the love of knowledge" than a mere job to be done by entrepreneurs, employees, or others who have independent funding.[14] In 1980, Genentech, a San Francisco based biotechnology company, issued shares of its stock on the over-the-counter market. Among its products are a hormone capable of stimulating human growth, mass produced human insulin which would allow a substantial reduction in cost of the treatment of diabetes, and interferon which may prove to be the long awaited "miracle" drug to combat cancer. The price of Genentech stock increased dramatically during the first day of trading, and some brokers even suggested that Genentech may in time be the next Polaroid or Xerox.[15]

It has been asserted that patenting new forms of life, as sanc-

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matter, *see* William D. Montalbano, *Vatican Finds Galileo 'Not Guilty'*, WASH. POST, Nov. 1, 1992 at A40.).

13. Lauro Martines, *The Trial of Galileo*, WASH. POST, Dec. 13, 1987, (Book World), at 3. *See also* MICHAEL SEGRE, IN THE WAKE OF GALILEO (1991); Lynn White, Jr., *Science and The Sense of Self: The Medieval Background of a Modern Confrontation*, DAEDALUS, Spring 1978, at 47; CARL SAGAN, COSMOS 143 (1980).

14. John Compton, *Science, Anti Science and Human Values*, 1 AMICUS 33 (1980). *See generally*, GEORGE P. SMITH, II, GENETICS, ETHICS AND THE LAW (1981).

15. *Investors Dream of Genes*, TIME, Oct. 20, 1980, at 72. While biotechnology stocks have recently turned in uneven performances, and Genentech no longer seems to be the market leader, this was not the case in the early 1980s. The potential profits derived from manipulating the genetic code - be it either to create new forms of life sufficient to clean up toxic chemical wastes or to produce anti-cancer agents on grand scale - spurred the then President Derek Bok of Harvard University to suggest that his University start its own genetic engineering firm. Strong faculty opposition, however, forced him to give up these plans. *A Firm No*, TIME, Dec. 1, 1980, at 59. *See* GEORGE P. SMITH, II, THE NEW BIOLOGY: LAW, ETHICS AND BIOTECHNOLOGY Ch. 1 (1989); IVER P. COOPER, BIOTECHNOLOGY AND THE LAW (1987). *See also* J. Madeline Nash, *A Bumper Crop of Biotech*, TIME, Oct. 1, 1990, at 92; Joan O'C Hamilton, *Biotech: America's Dream Machine*, BUS. WK., March 3, 1992, at 66; Michael Waldholz & Hilary Stout, *A New Debate Rages Over the Patenting of Gene Discoveries*, WALL ST. J., April 17, 1992, at 1 (biotechnology will generate $50 billion in annual revenue by the year 2000).

tioned by the United States Supreme Court,[16] will be guided by short term profit motives rather than sound philosophical principles.[17] However, scientific knowledge is not, in and of itself, an absolute end. The thrust and purpose of patenting new life forms are basically technological and are essentially political. Because the etiology of new life forms is political, both its costs and its benefits are, of necessity, of public interest and concern.[18]

Pure scientific inquiry does not produce an economic exploitation of nature; only man's use of the truths of scientific inquiry does. With the methodological style of nature, science seeks to demonstrate causal relations among events. Thus, the laws of science state that whenever X occurs or varies in a particular way, Y will similarly occur or vary in a particular way. This phenomenon has been aptly termed "a formula for action." Its practical application awaits only an individual's decision that it might be economically advantageous to try to mobilize X's to produce Y's.[19] Science promises truth, not peace of mind.[20] Yet liberty to extend knowledge is never to be regarded as absolute - but rather as has been seen, undergoes limitation when it conflicts with other values.[21]

The spirit of inquiry and analysis must focus as well on the additional parameters of the scientific imperative to explore truth; with the reality of this inquiry being shaped in turn largely by the United States patent laws and administrative interpretations and, more specifically, by the United States Supreme Court in its holding allowing new forms of life created in a laboratory to be patented. The ultimate purpose of this investigation is to refute the arrogance of power theory expressed as being implicit in the current studies of the vast potential for the positive achievement of good through harnessing the "New Biology." Thus, it will be demonstrated, that what has been dismissed as but a magnificent obsession for power, profits and immortality has, in truth, a far more intrinsic potential

16. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

17. George J. Annas, *Life Forms: The Law and the Profits*, HASTINGS CENTER REP., Oct. 1978 at 21, 22. *See also* Stephen P. Stich, *The Rewards and Risks of Studying Genes*. HASTINGS CENTER REP., April 1986, at 39. *But see* William Booth, *Biomedical Scientists Cite Funding 'Crisis'*, WASH. POST, June 29, 1990, at A25.

18. Compton, *supra* note 14, at 37.

19. *Id.*

20. *See* Philip J. Hilts, *'Rules' Drawn for Marketing Gene Research*, WASH. POST, Mar. 28, 1982 at A1; George F. Will, *The Spiral of Patents Pending*, WASH. POST, June 22, 1980, at D7.

21. Julius Stone, *Knowledge, Survival, and the Duties of Science*, 23 AM. U. L. REV. 231, 238 (1973).

for good and reward for the scientific community and the greater world community.

Improvement of man's genetic endowment by striving for positive propagation of those with a superior genetic make-up or, conversely, delimitation of those with negative genetic inheritance has always been a primary concern in the field of genetics.[22] If the quality of life in some way may be improved or advanced by use of law as it relates to genetics, then such must be undertaken. No longer does the Dostoevskian quest to give life meaning through suffering become an inescapable given. By and through new scientific advances in the field of genetics and successes with *in vitro* fertilization, the real potential exists to prevent, in large measure, much human suffering *before* it manifests itself in or through life.

Altering Human Evolution

Today, man is in a position not only to alter the social and environmental conditions of the universe, but also to change his very essence.[23] The mythology of the Minotaur and the Centaur, half man and half animal, may well become the reality of the twenty-first century. Indeed, not only is modern medicine attempting to create man-animal combinations, but also man-machine combinations, or cyborgs.[24] Plastic arteries, artificial limbs, and pacemakers highlight the efforts of modern science to replace diseased or worn out parts of the human body.[25]

Efforts to construct or engineer biologically functional bacterial plasmids *in vitro* exemplify the relatively new technology of recom-

22. *See* GEORGE P. SMITH, II, GENETICS, ETHICS AND THE LAW 1 (1981). *See also* Alexander M. Capron, *Which Ills to Bear?: Reevaluating the "Threat" of Modern Genetics*, 39 EMORY L.J. 665 (1990); George P. Smith, II, *Eugenics and Family Planning: Exploring the Yin and The Yang*, 8 U. TASMANIA L. REV. 4 (1984).

23. JOSEPH FLETCHER, THE ETHICS OF GENETIC CONTROL: ENDING REPRODUCTIVE ROULETTE (1974). *See* George P. Smith, II, *Manipulating the Genetic Code: Jurisprudential Conundrums*, 64 GEO. L. J. 697 (1976). *See also* Sissela Bok, *Freedom and Risk*, DAEDALUS, Spring 1978, at 115.

24. Barnaby J. Feder, *The 'Pharmers' Who Breed Cows That Can Make Drugs*, N.Y. TIMES, Feb. 9, 1992, at F9 (animals artifically endowed with human genes may produce hormones for drug companies such as Genpharm International, Inc. and DNX Corporation within four years); Caryl Rivers, *Genetic Engineering Portends a Grave New Word*, SAT. REV., April 8, 1972, at 23; Leon Jaroff, *The Gene Hunt*, TIME, Mar. 20, 1989, at 62. *See generally* JUNE GOODFIELD, PLAYING GOD (1977); George P. Smith, II, *Intimations of Immortality: Clones, Cryons and The Law*, 6 U. N.S.W. L. REV. 119 (1983).

25. *See* SMITH, *supra* note 15 at ch. 5; *see* Malcolm Gladwell, *New Gene Therapy Procedure Reportedly Done Within Body*, WASH. POST, Sept. 14, 1990 at A17. *See generally* ARNOLD J. TOYNBEE, SURVIVING THE FUTURE (1971) and THE PROSPECTS OF WESTERN CIVILIZATION (1949).

binant DNA.[26] Regarded as the most significant step in the field of genetics since 1953, research in this technology will facilitate identification of every one of the 100,000 genes in the human cell. Armed with this information, efforts could be directed toward replacing defective genes with healthy ones. Thus, the hope is that by making such replacements, genetic diseases such as hemophilia and sickle-cell anemia could be conquered.[27] Indeed, the plenitude of new products of nature that could substantially improve the human condition is staggering to the imagination.

The National Institute of Health (NIH) has taken a conservative view of the limits of safety review required by those institutions receiving federal grant monies to experiment in DNA. In 1980, two hundred representatives from the scientific community called upon NIH to loosen the restriction on gene-splitting experiments conducted in the United States. The scientists expressed the growing agreement that DNA research carries fewer risks than had once been thought.[28]

The central question which arises in relation to the current scientific advances is whether genetic engineering should be promoted and encouraged as a basic recognition of the freedom of scientific inquiry and right of privacy. Significant potential dangers are present in conjunction with the almost limitless opportunity for scientific advancement within the technology of recombinant DNA, commonly referred to as genetic engineering. The fear that the proverbial "mad scientist," working independently or with an enemy foreign power, could isolate and then proceed to duplicate a cancer organism and possibly place it in public water supplies is not easily dismissed. Acts of thoughtless negligence in a laboratory could result in the "escape" of a deadly microbe, which in turn could give

26. DNA is the basic genetic material that transmits inherited characteristics.

27. Matt Clark, Shannon Begley & Sharon Hager, *The Miracle of Spliced Genes*, NEWSWEEK, Mar. 17, 1980, at 62; *See generally* THE CODE OF CODES (Daniel J. Kevles et al. eds, 1992) (Scientific and Social Issues in the Human Genome Project and the possibility of DNA-based medicine); Robert F. Baker & Wendy G. Clough, *The Technological Use and Methodology of Recombinant DNA*, 51 S. CAL. L. REV. 1009 (1978) (explaining the DNA process and advances in genetic research).

28. *Scientists Want Limit Dropped on Gene Splitting Experiments*, WASH. POST, Nov. 26, 1980, at C3. *But see*, Cheryl M. Fields, *Bizarre Circumstances Surround Chance Cloning of Banner Virus*, CHRON. OF HIGHER EDUC., Aug. 25, 1980, at 1, col. 1 (in violation of federal guidelines that bar genetic copying, a researcher at the University of California at San Diego cloned a virus); Irving Holtzman, *Patenting Certain Forms of Life: A Moral Justification*, HASTINGS CENTER REP., June 1979, at 9 ; Rebecca S. Eisenberg, *Patenting The Human Genome*, 39 EMORY L.J. 721 (1990). *See also NIH May Accept Ban on Patenting Genes*, WALL ST. J. Aug. 27, 1992 at B4.

rise to a "parade of horribles." Chance occurrences are always inherent in any scientific intervention.[29] When the chance of harmful accident is calculated, the primary consideration is whether the merit of the intervention justifies beginning or continuing the experiment.[30]

Genetic engineering, viewed as an instrument to revolutionize, limits the effect of natural selection and replaces it with programmed decision making. Programmed decision making facilitates, rather than impedes, rational thinking. Is it shameful to acknowledge that man has the capability to be in control of himself? The lack of control over the years has spawned a type of "evolutionary wisdom" which, in turn, resulted in the bubonic plague, smallpox, yellow fever, typhoid, diabetes and cancer. Today, the quest for maximum efficient utilization of biological and medical knowledge represents one of the tenets of the so-called "evolutionary wisdom."[31]

A number of Post-Darwinians in the scientific community assert that there is no wisdom in evolution, only chance occurrence. Few, if any, would be willing to accept unconditionally all that nature bestows, particularly disease. Consequently, science finds itself in the position of trying to both influence and, in many cases, control the process of evolution. Some would go so far as to suggest that dangerous knowledge is never half as dangerous as dangerous ignorance.[32]

The sanctity of creation and the fundamental right of privacy in procreation, which is an acknowledged basic or fundamental freedom, may be altered by compelling state interests.[33] Is there a more

29. Robert Neville, *Philosophic Perspectives on Freedom of Inquiry*, 51 S. CAL. L. REV. 1115, 1128-29 (1978).

30. *See generally* Carl Cohen, *Restriction of Research with Recombinant DNA: The Dangers of Inquiry and The Burden of Proof*, 51 S. CAL. L. REV. 1081, 1098 (1978); Mark W. Lauroesch, Note, *Genetic Engineering: Innovation and Risk Minimization*, 57 GEO. WASH. L. REV. 100 (1988).

31. Joseph Fletcher, *Ethics and Recombinant DNA Research*, 51 So. CAL. L. REV. 1131, 1139, (1978). Fletcher observes that there is nothing fundamentally unnatural or intrinsically wrong, or hazardous for the species, in the ambition that drives man to develop the technology to understand himself. It would in fact seem more offensive to fail to use and develop man's natural curiosity and talent for asking questions or worse to try to suppress it. "This is the greater danger of our species, to try to pretend that we are another kind of animal . . . and that the human mind can rise above its ignorance by simply asserting that there are things it has no need to know." Lewis Thomas, *Notes of a Biology Watcher: The Hazards of Science*, 296 NEW ENG. J. MED. 324, 328 (1977).

32. *See* Stephen Toulmin, *Science and Ethics: Can They Be Reconnected*, U. CHICAGO MAG., Winter 1981, at 2 .

33. *See* Roe v. Wade, 410 U.S. 113 (1973); George P. Smith, II, *Procreational Auton-*

compelling state interest than the desire to stop a "chromosomal lottery" which saddles the economy each year with four million Americans born with diabetes or fifty thousand born with discernible genetic diseases?[34] State interests in minimizing human suffering and maximizing the social good should be properly validated.[35]

Opponents of unrestricted genetic research specifically attack its proponents as being both scientifically and socially irresponsible, and the ultimate promoters of a serious environmental disaster.[36] They suggest that nature has developed strong barriers against genetic interchanges between species, and that extreme caution ought to be used during experimentation in this area.[37] Others argue that mankind's genetic inheritance is its greatest and most indispensable treasure which must be protected and guaranteed at any cost. These opponents submit that the evolutionary wisdom of the ages must not be irreversibly threatened or abridged in order to satisfy the ambition and professional curiosity of some members of the scientific community.

Autonomy, self-determination, and a basic sense of freedom must be tempered by logic, objectivity, and a disinterested search for knowledge; a search that may result in the minimizing of human suffering and maximizing of social good.[38] But what is the social good in this question? It is suggested that the social good, within this context, could be equated with an economic policy that lessens the financial burden on citizens and supports and maintains genetically defective citizens. The wisest policy is, by consensus, that which promotes a goodsocial, economic or otherwisefor the greatest number. Thus, human need and well-being shape the degree of positive good resulting from one policy as opposed to another.[39] Alternatively, a determination could be made in order to structure what is right or wrong, good or evil, according to whether the consequences of an act or public policy add to, or detract from, the aggre-

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omy v. State Intervention: Opportunity or Crisis for a Brave New World?, 2 NOTRE DAME J. L. ETHICS & PUBLIC POL'Y 635 (1986); George P. Smith, II & Roberto Iraola, *Sexuality, Privacy and The New Biology*, 67 MARQ. L. REV. 63 (1984).

34. *See* Glass, *The Effect of Changes in the Physical Environment on Genetic Change*, in GENETICS AND THE FUTURE OF MAN 43 (JOHN ROSHANSKY ed. 1966).

35. *See* SMITH, *supra* note 14 at 2.

36. *See generally* TED HOWARD & JEREMY RIFKIN, WHO SHOULD PLAY GOD? (1977); Philip J. Hilts, *Genetic Scientist is Punished for Test Violations*, WASH. POST, March 23, 1981, at A1.

37. Robert L. Sinsheimer, *Recombinant DNA - On Our Own*, 26 BIOSCIENCE 599 (1976).

38. Robert L. Sinsheimer, *Potential Risks, in* RESEARCH WITH RECOMBINANT DNA (National Academy of Science ed., 1977).

39. June Goodfield, *supra* note 24 at 71.

gate human well-being.[40]

Ultimately, the decision for or against a policy is going to be tied to development and maintenance of an *a priori* standard of ethics (where, in theory, a balancing occurred before the standard was set), or to a situational ethic by which the consequences, *pro* and *con*, equities or inequities, of each proposed action will be carefully weighed and a conclusion with an ethical posture or structure of a standard of *modus operandi*[41] will be reached.

Encouraging Experimentation

Recognizing that a sustained level of progress for society would depend upon a continuing standard of technological evolution as well as individual technological contributions of exceptional merit and benefit, the Founding Fathers endeavored to codify this attitude within the United States Constitution. By structuring a system of checks and balances within the Constitution which would promote both perspectives, contributions which were truly exceptional could be promoted by grant of a limited monopolization as authorized by the Patent Clause.[42] However, the grant of limited monopolization was intended to be consistent with the guarantees of the fifth and the fourteenth amendments, that recognize the right of all citizens to develop their individual skills in pursuit of a trade or calling, and thus establish this right as an inalienable property right.[43]

There is a long history of efforts to legitimize monopolies for patents of unworthy inventions. To its credit, the United States Supreme Court has thwarted these efforts and has recognized and enforced the Constitutional mandate to allow the unfettered growth and natural evolution of technology.[44]

On June 16, 1980, by a 5-4 vote, the United States Supreme Court decided that new forms of laboratory life were eligible for

40. *See* Fletcher, *supra* note 31, at 1131-39.

41. *Id.* at 1138-39.

42. *See generally* TOM L. BEAUCHAMP & LEROY WALTERS, CONTEMPORARY ISSUES IN BIOETHICS (1978); George P. Smith, II, *Uncertainties on the Spiral Staircase: Metaethics and The New Biology*, 41 THE PHAROS 10 (1978).

43. *See* Edward S. Irons & Mary Helen Sears, *Patent 'Re-examination': A Case for Administrative Arrogation*, 1980 UTAH L. REV. 287-88. By the Patent Clause, Congress is authorized "[t]o promote the Progress of Science and useful Arts, by securing for limited Times . . . Inventors the exclusive Right to their . . . Discoveries". U.S. CONST. art. I, § 8, cl. 8.

44. *See* Sakraida v. Ag Pro, Inc., 425 U.S. 273, 279 (1976) (citing Graham v. John Deere Co., 383 U.S. 1, 17 (1966)); Atlantic Works v. Brady, 107 U.S. 192, 200 (1882). Interestingly, about 65-70% of litigated patents are invalidated. BEAUCHAMP & WALTERS, *supra* note 42, at 305.

patents.[45] The decision may be regarded as a ratification of some of the accomplishments of the "biological revolution" which has allowed a broader understanding of life and promoted a greater ability to manipulate various forms. However, both the majority opinion and the dissent stressed that they address only the question of whether the current patent laws evinced a congressional intent to deny patents to those inventions determined to be alive.[46] More particularly, the Court chose to tie itself to the United States Code section which provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[47] Out of this statute emerged the issue of whether a manufactured microorganism constituted "a 'manufacture' or 'composition of matter' within the meaning of the statute."[48]

Dr. Ananda M. Chakrabarty, a micro-biologist employed by the General Electric Corporation, engaged in research in which he succeeded in manufacturing a new microorganism, not found in nature, which is effective in breaking up oil spills. This genetically engineered strain of *pseudomonas* is made by combining (or cross breeding) four strains of oil eating bacteria into one man-made scavenging microorganism which combines the beneficial properties of each of its four parent bacteria. Each of the four strains digest particular hydrocarbons in a mixture of oil and water, such as is found in petroleum spills. Useful by-products of water, carbon dioxide and bacterial protein which are nutritious to inhabitants of the ocean, remain. Dr. Chakrabarty demonstrated that this manufactured "superstrain" is much more efficient in digesting oil than a mixture of the four individual bacteria. Another advantage is that this microorganism, if it "escaped," would not be able to thrive in gas tanks or in the oil fields of the earth and wreak uncontrolled

45. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

46. Justice Brennan, writing in dissent, surveyed the Patent Act of 1793, as re-enacted in 1952, the Plant Patent Act of 1920, and the Plant Variety Protection Act of 1970 and concluded that there existed a strong congressional limitation against patenting bacteria. "It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern." *Id.* at 322. For those who have followed Justice Brennan's judicial philosophy, this position, which calls for judicial restraint, is most interesting and unusual. In the past, he has been the judicial activist and Chief Justice Burger the apostle of judicial restraint. In *Chakrabarty*, the roles were reversed.

47. 35 U.S.C. § 101 (1976).

48. Diamond v. Chakrabarty, 447 U.S. at 307.

environmental havoc on the ecosphere.[49] The Chakrabarty bacterium had already been granted a patent in Britain, which had followed several European nations in recognizing both plants and animals as patentable.[50]

The patent application of Chakrabarty and General Electric was for a manufactured microorganism product not found in nature as well as a process of using the microorganism, on a carrier, to digest oil spilled in water. The United States Patent Office rejected the product claim, but allowed a portion of the process claim. The rationale for rejection of the product claim was that a living organisma naturally occurring product of natureas this was determined to be, was not within the classes of subject matter which are patentable. The patent office reached this conclusion because there was no mention of such a class in the controlling statute or in the statute's legislative history. This decision was upheld by the Patent Office Board of Appeals, but the United States Court of Customs and Patent Appeals reversed, and the Patent and Trademark Office appealed to the United States Supreme Court.[51]

In the past, the Patent Office has included living things within the statutory subject matter. For example, in 1873, United States Patent No. 141,072 was issued to Louis Pasteur. Claim two of the patent application reads: "Yeast, free from organic germs of disease, as an article of manufacture."[52] There are other examples, in other patents, of claims having been granted for viruses and cultures.[53]

Today, there are more than one hundred patent applications related to products of genetic engineering.[54] *Chakrabarty* sets the

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49. Rick Gore, *The Awesome Worlds Within a Cell*, 150 NAT'L GEOGRAPHIC 355, 374-75 (1976).

50. *See generally* Thomas D. Kiley, *Common Sense and the Uncommon Bacterium — Is 'Life' Patentable?*, 60 J. PAT OFF. SOC'Y 468 (1978).

51. Application of Chakrabarty, 571 F.2d 40 (C.C.P.A. 1979) *dismissed* 439 U.S. 801 (1978) *rev'd sub nom.* Application of Bergy, 596 F.2d 952 (C.C.P.A. 1978), *cert. granted*, 444 U.S. 924 (1979). *See* Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS 399 (1988).

52. Diamond v. Chakrabarty, 447 U.S. 308, 314 at n.9 (1980). *See also* Donald G. Daus, Robert T. Bond & Shep K. Rose, Student Papers, *Microbiological Plant Patents*, 10 IDEA 87 (1966).

53. *Id.* at 94 n. 36. *See* Iver P. Cooper, *Patent Protection for New Forms of Life*, 38 FED. BAR. J. 34 (1978); Rudolf F. Kip, Jr., *The Patentability of Natural Phenomena*, 20 GEO. WASH. L. REV. 371 (1952).

54. *See* Donald D. Daus, *Patents for Biotechnology*, 26 IDEA 263 (1985-86); Marcia Barinoga, *Making Transgenic Mice: Is it Really That Easy?*, 245 SCIENCE 590 (1989); Waddell A. Biggart, *Patentability in the United States of Microorganisms, Processes Utilizing Microorganisms, Products Produced by Microorganisms and Microorganism Mutational and*

pace for a wide variety of new "man-made organisms which can facilitate socially desirable processes such as growing wheat in arid lands, leeching ores to assist mining companies in reaching remote part of the earth, and producing a "bug" that will ferment corn starch or corn syrup into ethanol, an alcohol used in both whiskey and gasohol. There is also a patent application for a bacterium that metabolizes ethylene into ethylene glycol (antifreeze).[55]

As noted previously, the major thrust of the decision of the United States Supreme Court in *Chakrabarty* is tied to the interpretation of the term "manufacture" as it appears in the federal patent code. Observing that Thomas Jefferson's Patent Act of 1793 stressed its coverage to "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof)," Chief Justice Burger, writing for the majority, defined manufacture as "the production of articles for use from raw materials prepared by giving to these new materials new forms, qualities, properties, or combinations whether by hand labor or by machinery."[56] Citing approving precedent defining "composition of matter" as including "all compositions of two or more substances . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids," the Chief Justice concluded that the *Chakrabarty* microorganism qualifies as being within patentable subject matter.[57] The claim is particularly forceful since it is for a product of human ingenuity which is non-natural in its occurrence.[58]

In response to the argument that microorganisms cannot be patentable without express congressional authorization, Chief Justice Burger declared that Congress had already defined what was patentable subject matter in Section 101 of the Act, and that it was for

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Genetic Modification Techniques, 22 IDEA 113 (1981-82). Some corporations have been quick to market genetically engineered products. For example, DNA Plant Technology Corp. received a patent for a genetically engineered celery, which it calls "Novel Celery Lines With Increased Stick Yield." The patent has been licensed to Freshworld, DNA Plant Technology Corp.'s branded-produce joint venture with Du Pont Co. for use in the Vegi Snax line of snacking vegetables. *DNA Plant Technology Corp.*, WALL ST. J., June 26, 1992 at B6.

55. *See generally* Dorothy Nelkin, *Threats and Promises: Negotiating the Control of Research*, DAEDALUS, Spring 1978, at 191; Leslie Roberts, *Ethical Questions Haunt New Genetic Technologies*, 243 SCIENCE 1134 (1989).

56. 447 U.S. at 308 (1980).

57. *Id.* at 308-309.

58. *Id.* at 310. *See generally*, Richard Delgado & Darrel R. Miller, *God, Galileo and Government: Toward Constitutional Protection for Scientific Inquiry, in* 1 ETHICAL, LEGAL AND SOCIAL CHALLENGES TO A BRAVE NEW WORLD 231 (George P. Smith, II ed., 1982).

the courts to define that provision. Finding no ambiguity in the statutory provisions and stressing the broad constitutional and statutory goal of promoting "the Progress of Science and the useful Arts," Chief Justice Burger adhered to his position that the definition the Court gives to section 101 is consistent with the goals of the Act.[59]

The Court declined to acknowledge the "grave risks" or the "gruesome parade of horribles" which the Patent Office argued that the Court should weigh in deciding whether the Chakrabarty invention is patentable.[60] Although acknowledging that "genetic" research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of life," the Court concluded that neither the grant nor the denial of patents on microorganisms will end advance in genetic research nor "deter the scientific mind from probing into the unknown any more than Canute could command the tides."[61] The Court stated unequivocally that scientific arguments against advancements in this field are matters of "high policy" which should be considered by the legislative process which balances and places in proper perspective the various competing values and interests of all parties.[62] The Chief Justice concluded by noting that if the Court had misconstrued the provisions of Section 101, all that Congress needed to do was to amend the statute to exclude organisms which are produced by genetic engineering from the protection of the patent laws.[63]

Despite the Court's disclaimer that its action was purely constructive in naturemerely an interpretation of a statutory mandateit did attempt to validate a new national policy. While invoking the Jeffersonian concept of ingenuity in patent creativeness, it came down four-square on a policy encouraging experimentation into the "New Biology" despite the possible risk to mankind. Thus, while disclaiming the application of a balancing test, it, in effect, performed one. It correctly decided that the utility of the good that will flow from research and experimentation into the varied fields of the "New Biology" far outweighs the potential harm accruing as a consequence of such undertaking. This is an eminently fair and reasonable position.

59. 447 U.S. at 315.
60. Id. at 316-317.
61. *Id.*
62. *Id.* at 317.
63. *Id.* at 311.

A Further Innovative Application

In May, 1987, the United States Patent and Trademark Office announced that it "considers non-naturally occurring nonhuman multi-cellular living organisms, including animals, to be patentable subject matter."[64] This policy was viewed by the Patent Office as an effort to keep pace with the startling new advances in biotechnology, and thereby encourage innovation and not determine its ethical implications. Others, such as animal rights advocates, were concerned that animals were being considered as products and not sentient beings.[65] Some feared that the new policy would enable a select number of biotechnology companies to dominate the livestock industry, thereby eliminating small independent breeders and threatening to eliminate genetic diversity among farm animals,[66] since with patents the central issue becomes who either owns, or is in control of breeding livestock.[67]

Theologians quarrelled with the Patent Office policy because it not only equated heavenly made creatures with manufactured goods of the market place, but took a giant step on the slippery slope that would lead to the patenting of genetically altered human beings and man's full assumption of God-like powers. The clear specification of the policy that its application was only for "nonhuman life" was of no assurance here.[68] Informed members of the scientific community, however, saw the Patent Office as merely continuing the reasonable exploitation of nature.[69]

The Transgenic Animal Patent Reform Act was passed in 1988.[70] The Act excludes human beings from patentable subject matter, provides immunity for patent infringement to farmers who purchase patented farm animals and seek to reproduce them, and also seeks to clarify the Patent and Trademarks Office's authority to require biological materials deposits from patented animals.[71] The

64. Claudia Wallis, *Should Animals be Patented?*, TIME , May 4, 1987, at 110. *See also* TIM INGOLD, WHAT IS AN ANIMAL? (1988).

65. *Id.*

66. *Id.*

67. *Id. See also* Philip Elmer-Dewitt, *The Perils of Trading on Heredity*, TIME, Mar. 20, 1989, at 70-71.

68. *Id.*

69. *Id.*

70. Pub. L. 100-703, tit. II, § 201, 102 Stat. 4676, 35 U.S.C. § 271 (1988). *See generally* Diana A. Mark, Comment, *All Animals Are Equal, But Some Are Better Than Others: Patenting Transgenic Animals*, 7 J. CONTEMP. HEALTH L. & POLICY 245 (1991).

71. *House Passage of Animal Patent Bill*, 36 Pat. Trademark & Copyright J. (BNA) No. 897 at 499 (Sept. 15, 1988). On March 22, 1989, Representative Robert Kastenmeier introduced H.R. 1556, that would limit the rights of animal patentees beyond the restrictions

most serious defect of this law is that it fails to define the term, "human being." Thus, the extent to which genetic material constitutes a human being is an open question.

> "Should an animal that contains one-half of a human code be considered human? How about one-quarter human genetic material? Should genetically altered fetuses be considered patentable subject matter under current patent law? Although such animals are not being patented, . . . such technology will exist in the near future."[72]

It is expected that the near future of biotechnology will give rise to work in laboratories in the United States where virus and bacteria genes will be transferred to plants in an effort to enable them to produce their own particular insecticides or fertilizers. After field testing, these "transgenic" plants will be used by farmers in the place of conventional crop varieties.[73] Further successful research will be undertaken that manipulates the primordial cells producing sperm and eggs to enable breeders to determine the sex and other preferred characteristics of their animals; and routine gene transplants from one species to another will be accomplished routinely.[74]

As discussed previously,[75] these and similar concerns over patenting life were initially raised with the *Chakrabarty* decision.[76] Since no catastrophic events have followed in the aftermath of *Chakrabarty*, and none are expected from this new policy of the United States Patent and Trademark Office, the on-going debates over the long range effects of genetic engineering and its ethical constraints will be of little value in halting the momentum of scientific inquiry, experimentation and advancement of biotechnology.

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imposed on holders of conventional patents, with exemptions being granted to small family farmers, certain larger farmers and researchers who reproduce these animals for non-commercial purposes. His second Bill, H.R. 1557, seeks to regulate the use of genetically engineered animals in agricultural activities (101st Cong., 1st Sess., 135 CONG. REC. H830 (daily ed., Mar. 22, 1989). Subsequently, H.R. 3247 was introduced on September 12, 1989, by Representative Cardin that would impose a moratorium on the patenting of animal life until a proper regulatory procedure is established. (101st Cong., 1st Sess., 135 CONG. REC. E3008 (daily ed., Sept. 12, 1989). Finally, Senator Mark Hatfield introduced S. 2169 in the Senate on February 26, 1990, that seeks to set a five-year moratorium on granting transgenic animal patents. (101st Cong., 1st Sess., 136 CONG. REC. S1611 (daily ed., Feb. 26, 1990).

72. 134 CONG. REC. H7439 (daily ed. Sept. 13, 1988), (Remarks of Rep. C. Rose).

73. Keith Schneider, *A Patent on Life Forms Gets Genes Into Business*, INTL. HERALD TRIBUNE, June 9, 1987, at 1.

74. *Id. See also*, Robert S. Wasowski, *The Evolution of Patentable Compositions of Matter: The United States Patent Office Accepts Genetically Altered Animals as Patentable Subject Matter under 35 U.S.C. Section 101*, 2 AD. L. J. 309 (1988).

75. *See supra* notes 18-41.

76. *See generally* Reagen Anne Kulseth, Note, *Biotechnology and Animal Patents: When Someone Builds a Better Mouse*, 32 ARIZ. L. REV. 691 (1990).

III. VALUES IN CONFLICT

Some would seek to abandon science and reason in favor of mysticism, hermeneutics and transcendental rapture. Sadly, they fail to comprehend that ignorance, not knowledge assures misery; and that the employment of science for inhumane reasons, not science in and of itself, threatens global survival. Reduced to its most fundamental level, then, what is seen is that the pivotal questions confronting the science of human experimentation are two in number: who will *control* its products, and what purposes will be employed to achieve this end.[77]

The improvement of human well-being has been, for the most part, the single motivating force in the quest to ensure that all citizens, especially young children, will be safe from all forms of disease; not only genetic and congenital disorders, but uterine infections and a formidable host of other birth defects.[78] Since the 1930s, for example, human fetal tissue has been an invaluable research tool for molecular biologists as a source of human cell lines. In turn, these cell lines have been widely used in advanced research on viruses, and in the preparation of vaccines (notably, the polio vaccine) against them. More recently, successful research has been conducted on fetal tissue transplants in living subjects for therapeutic purposes, and for developing treatments for Parkinson's disease, diabetes and radiation-induced anemia. What makes fetal tissue soparticularly useful for transplantation is the fact that it not only grows rapidly and is very adaptable, but induces a limited immune response from the host.[79]

The Federal Position

Both as a response to Louise Brown's extracorporeal birth in

77. JOSEPH FRANCIS FLETCHER, HUMANHOOD: ESSAYS IN BIOMEDICAL ETHICS 93 (1979). See 1 ETHICAL, LEGAL & SOCIAL CHALLENGES TO A BRAVE NEW WORLD, Ch. 10 (G. Smith ed. 1982); *see also Commercialization of Biotechnology: Hearings Before the Subcomm. on Technology and Competitiveness of the House Comm. on Science, Space and Technology*, 102 Cong., 1st Sess. 70-75 (1991) (statement of Lawrence Busch, Michigan State Univ.).

78. *Id. See also* Eisenberg, *infra* note 114.

79. Henry Greely et al., *The Ethical Use of Human Fetal Tissue in Medicine*, 320 NEW ENG. J. MED. 1093 (1989). It is between the sixth and eleventh weeks of gestation that nearly eighty percent of all individual abortions are performed. Thus, neural and other tissue are at a sufficiently developed state that it may—with success—be retrieved and transplanted. For those abortions performed between fourteen and sixteen weeks, pancreatic tissue is of particular value in diabetes research. John A. Robertson, *Rights, Symbolism and Public Policy in Fetal Tissue Transplants*, HASTINGS CENTER REP., December 1988, at 5.

1978, and to a grant application for *in vitro* fertilization (hereinafter "IVF") research, the then Department of Health, Education and Welfare (now the Department of Health and Human Services) and its Ethics Advisory Board decided to study the complex ethical, legal, social and scientific issues raised by the IVF process.[80] The final report of the Department was ultimately "buried in the bureaucracy."[81] Yet today, given the sometimes strident pro-life mood of a vocal segment of society, there is pessimism that a strong positive movement will occur at the federal regulatory level.[82] Due largely to the leadership of former Congressman (now Senator) Albert Gore of Tennessee, hearings were conducted in August, 1984, on the issue of embryo transfers and the legal, ethical and medical responses to such procedures.[83] Although no firm or conclusive steps were taken as a consequence of these hearings, they served to focus attention on the need for continuing dialogue in this area.

Because of a *de facto* moratorium set in 1975, no federally funded research has been undertaken on IVF.[84] Even though the 1979 Report of the Ethics Advisory Board of HEW concluded that federal support of research on humans designed to establish the safety and the effectiveness of IVF procedures would be ethically permissible so long as certain conditions were met,[85] the Report has never been accepted nor the moratorium ended; there is no real likelihood such action will be taken soon.[86]

It should be noted that the involvement of the federal govern-

80. Ethics Advisory Board of the Department of Health, Education and Welfare, Report and Conclusions: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer, 44 Fed. Reg. 35,033 (1979). *See* Richard A. McCormick, *Who or What is the Preembryo?*, KENNEDY INST.. ETHICS J., March 1991, at 1.

81. Harry D. Krause, *Artificial Conception: Legal Approaches*, 19 FAM. L.Q. 185, 190 (1985).

82. This pessimistic, although realistic, view is tied to a perception that it would be far better to hold in abeyance any strong movement at this time for fear of its possible linkage with the right-to-life controversies and would thus give rise to the real possibility that it would never be allowed to be evaluated in a calmer atmosphere. Susan Abramowitz, *A Stalemate on Test-Tube Baby Research*, HASTINGS CENTER REP., February 1984, at 5.

83. *See Hearings On Human Embryo Transfer, Subcommittee on Investigations and Oversight, U.S. House of Representatives' Committee on Science and Technology*, 98th Cong., 2nd Sess. 142 (1984).

84. Abramowitz, *supra* note 82.

85. Ethics Advisory Board, *supra* note 80 at 35,057. Among these conditions were that the embryo be sustained in vitro beyond the implantation stage and that IVF, followed by embryo transfer, be used only by married couples who had donated their sperm and ova. Abramowitz, *supra* note 82.

86. Abramowitz, *supra* note 82 at 6. *See* John C. Fletcher & Kenneth J. Ryan, *Federal Regulations for Fetal Research: A Case for Reform*, 15 L. MED. & HEALTH CARE 126 (1987).

ment and its Department of Health and Human Services is presently structured by general regulations protecting human subjects which apply to any IVF research, development, or other related activities that might in the future be conducted by the Department, or by the federal government outside the Department.[87] To ensure additional protection in research projects that involve fetuses and/or pregnant women, the Ethics Advisory Board of the Department will be required to review every such proposal for IVF "as to its acceptability from an ethical standpoint."[88]

Subsequent specific protections have been provided to fetuses who are the subject of proposed experimentation and IVF research.[89] Although limited to research efforts funded in whole or in part by the federal government,[90] these guidelines make a significant distinction with regard to potential legal rights of implanted embryos.[91] The distinction is apparent in the definition of a fetus as "the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test. . .)."[92]

As a consequence of this structured definition, research undertaken on fetuses *in utero* and *ex utero* is prohibited unless the purpose of the activity is to either meet the particular health needs of the at-risk fetus, or there is minimal real or potential harm to the fetus by the research, and the purpose is to obtain biomedical knowledge not otherwise obtainable.[93] Research undertaken on non-viable fetuses *ex utero* is prohibited unless either vital functions will not be maintained artificially, experimental activities that would terminate vital functions are not used, or the research purpose is to obtain otherwise unobtainable significant biomedical knowledge.[94] The obvious implication of these restrictions on embryonic and fetal research is that the scientific pursuit of mankind is significantly handicapped. Private research into the mysteries and the opportunities of the new reproductive biology continues. But,

87. 45 C.F.R. §§ 46.101-124, 46.301-306(g), 46.401-409 (1991).

88. 45 C.F.R. § 46.204(d) (1991). *See also* 45 C.F.R. § 46.205 (1991).

89. 45 C.F.R. §§ 46.102-206 (1985). In Vitro Fertilization is defined as "any fertilization of human ova which occurs outside of the body of a female, either through admixture of donor human sperm and ova or by any other means." Section 46.203(g) (1991).

90. 45 C.F.R. § 46.101(a) (1991).

91. Grace Ganz Blumberg, *Legal Issues on Nonsurgical Human Ovum Transfer* 251, J.A.M.A. 1178 (1984).

92. 45 C.F.R. § 46.203(c) (1991).

93. 45 C.F.R. §§ 46.208(a) (1)-(2) (1991).

94. 45 C.F.R. §§ 46.209(b) (1)-(3) (1991).

without a balanced regulator scheme and sources for federal research funding, the initiative and the momentum for scientific advancement is curtailed.

The Bush Administration Extension

On November 13, 1989, the Bush Administration, through Dr. Louis W. Sullivan, Secretary of Health and Human Services, advised the National Institutes of Health that, because of a belief that allowing federal scientists to conduct research using fetal tissue transplants would actually increase the incidence of abortion across the country, the ban on fetal-tissue research would be extended.[95] The Secretary stated that his department "should not be funding activities which encourage or promote abortion."[96] Even though limited in application to federal scientists, many members of the medical research community are of the opinion that extension of the fetal tissue research ban will produce a "chilling-effect" on this exciting field of research even for privately funded undertakings.[97] What is seen very clearly here is the inextricable relationship between abortion, fetal research[98] and experimentation and, even more importantly, a similar inextricability between politics and morality.[99]

A British Response

A more sophisticated and enlightened position has been taken by the British Government. In response to the findings of a national committee set up in 1988 to review guidelines for research use of fetuses and fetal material, the British Health Minister announced

95. Michael Specter, *Fetal-Tissue Research Ban Formally Extended*, WASH. POST, Nov. 3, 1989, at A5. (Editor's note: President Clinton has promised to lift the ban).

96. *Id.*

97. *Id. See* Michael Specter, *Abortion Issue Chills Research: Fetal Tissue Fund Ban Sidelines U.S. Experts*, WASH. POST, Mar. 27, 1990 at 1; Ruth Marcus, *Fetal Protection Policies; Prudence or Bias?*, WASH. POST, Oct. 8, 1990, at 1.

98. *Id.* Assistant Secretary of Health James O. Madison at the Department of Health and Human Services, told a congressional hearing April 1, 1990, that if the federal ban on funding of medical research using fetal tissue were lifted, women would be encouraged to have abortions. He observed that should the transplantation of fetal cells prove successful in treating epilepsy, diabetes and Parkinson's disease, "additional rationalization of [for] directly advancing the cause of human therapeutics cannot help but tilt some already vulnerable women toward a decision to have an abortion." Malcolm Gladwell, *HHS Official Defends Fetal-Tissue Policy*, WASH. POST, April 3, 1990, at A3.

99. George P. Smith, II, *Procreational Autonomy v. State Intervention: Opportunity or Crisis for A Brave New World?* 2 NOTRE DAME J. LAW, ETHICS & PUB. POL'Y 635, 638 (1986). *See generally*, Richard Locayo, *Pro Choice? Get Lost: Antiabortion Views Are a Must at Health and Human Services*, TIME, Dec. 4, 1989, at 43.

that the Government had accepted the central recommendations of the Committee which were issued July 26, 1989.[100] Separating abortion from the issue of how tissue from a dead fetus should be used, the Committee recommended that separate maternal consent be obtained for any act of abortion, and for the use of tissue from an aborted fetus. No direct contact would be permitted either between the abortion clinics or the institutions utilizing the tissue for research.[101] In an effort to safeguard against a possibility of "personality transfer" between a fetus and the recipient of fetal brain tissue, the recommendation was that in particular cases of nervous tissue, "only isolated neurons or fragments of tissue should be used for transplantation[s]."[102] The British Medical Association promptly endorsed the recommendations and the government posture, observing that this policy was totally compatible with what the members of the Association had freely "adopted covering physicians responsible for carrying out abortions, as well as those using fetal tissue to develop new therapies."[103]

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100. David Dickson, *Fetal Tissue Transplants Win U.K. Approval*, 245 SCIENCE 464 (Aug. 4, 1989). *See generally, BMA Guidelines on The Use of Fetal Tissue*, THE LANCET, (1988) at 1119 [hereinafter BMA Guidelines].

101. Dickson, *supra* note 100.

102. *Id.*

103. *Id.* The British Medical Association supports the following recommendations:

1. "Tissue may be obtained only from dead fetuses resulting from therapeutic or spontaneous abortion. Death of the fetus is defined as an irreversible loss of function of the organism as a whole.

2. UK laws on transplantation must be followed. The woman from whom the fetal material is obtained must consent to the use of the fetal material for research and/or therapeutic purposes.

3. Transplantation activity must not interfere with the method of performing abortions, nor the timing of abortions, nor influence the routine abortion procedure of the hospital in any way. Abortion must be performed subject to the Abortion Act, and any subsequent amendments thereof, uninfluenced by the fate of the fetal tissue. The anonymity of the donor should be maintained.

4. The generation or termination of a pregnancy solely to produce suitable material is unethical. There should be no link between the donor and the recipient.

5. There must be no financial reward for the donation of fetal material or a fetus.

6. Nervous tissue may be used only as isolated neurones or tissue fragments for transplantation. Other fetal organs may be used as either complete or partial organs for transplantation.

7. All hospital staff directly involved in the procedures—including the abortion—must be informed about the procedures involved." *Supra* note 95, BMA Guidelines.

In a free-vote on April 25, 1990, the British Parliament endorsed the continued practice of conducting *in vitro* medical and scientific research and experimentation on human embryos up to 14 days of age. It is commonly understood that the appearance of the "primitive streak" that represents the first physical embodiment of individuality, takes place the 14th day after fertilization. Experiments on human cloning and hybridization (or the creation of human-animal hybrids) were, however, outlawed. Michael White & Patrick Wintour, *Britain*

Since, like it or not, abortion is legal, is it not a simple deduction that it is ethically acceptable to use tissue from abortuses for research?[104] Rational, simple deductions are not the order of the day, however, when dealing with issues that are so emotionally charged. Inexplicable "feelings" and beliefs assume a mantle of sanctity not countenanced in other logical areas of discourse. It is nevertheless a legitimate act of faith to postulate that fetuses are persons.[105] The only difficulty with such a position is that there is no absolute way to prove or establish its validity. It can neither be verified nor falsified.[106]

A New Initiative?

Under a Bill entitled, "The National Institutes of Health Revitalization Amendments of 1991," introduced by Congressman Henry A. Waxman on March 20, 1991, the moratorium on federal funding of research on transplanting fetal tissue would be overturned. The bill provides that the National Institutes of Health, by and through the authority of the Secretary of Health and Human Services, would be given permanent authority to fund such research, provided that it complies with strict ethical guidelines prohibiting the sale of fetal tissues or directed donations.[107] The proposed legislation would preclude the Secretary from issuing a refusal to fund research determined to be scientifically valid on purely ethical grounds, unless a special ethics advisory panel first agreed that the research was unethical.[108]

Before research could be undertaken on donated human fetal tissue, the woman providing the tissue must execute a written statement acknowledging that the fetal tissue is being donated for use in authorized research; that the donation is to be made without regard to the identity of individuals who may ultimately be the recipients of the tissue; and that the female donor has not been informed of the identity of any recipients. In cases where tissue is provided as a

Gives The Go-Ahead for Embryo Research, 142 MANCHESTER GUARDIAN WKLY., April 29, 1990, at 1.

104. This was the initial posture taken by a review panel of the United States National Institutes of Health and presented to the then Assistant Secretary for Health, Robert Windom in 1988. Dickson, *supra* note 100.

105. Fletcher, *supra* note 77 at 96.

106. *Id. See* Smith, *supra* note 99; George P. Smith, II, *Intrusions of a Parvenu: Science, Religion and The New Biology*, 3 PACE L. REV. 63 (1982); Robert L. Sinsheimer, *The Presumptions of Science*, DAEDALUS, Spring 1978, at 23.

107. H.R. 1532, 102nd Cong., 1st Sess. (1991).

108. *Id.* § 101.

consequence of an induced abortion, the donor's statement must acknowledge that the decision to donate is made independent of the abortion decision, and not for the purposes of providing fetal tissue for research.[109]

If enacted into law, this proposed legislation would help to harmonize the needs of science with individual human rights. With the moratorium on fetal research and experimentation lifted, handicapped individuals with genetic or other disease, would no longer be told that the cure for their disease is "too controversial to study" or "too political to pursue."[110]

IV. TOWARD A STANDARD OF REASONABLENESS

The Supreme Court's actions in *Chakrabarty*, and the recent Patent and Trademark policy on the patentability of nonhuman life, give private corporations the incentive to invest further research into the fields of bio-chemistry, genetics, and eugenics. This incentive, and the anticipated result therefrom, satisfy the constitutional objective of early disclosure which expands the public domain of knowledge in these fields. There can be little doubt that patentability of microorganisms and nonhuman life forms is "Progress of the Useful Arts."

Man's dehumanization and depersonalization will not be fostered as a consequence of the continued quest for mastery of the genetic code, and the study and use of non-coital reproduction processes. Attendant to the freedom to undertake research into the exciting and fertile frontiers of the "New Biology" is a coexistent responsibility to pursue the work in a reasonable and rational man-

109. *Id.* § 111. H.R. 1532 was substituted and replaced by H.R. 2507 amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health and passed the House on July 25, 1991. The central focus of the replacement bill parallels the original H.R. 1532. *See* CONG. REC. (daily ed. July 25, 1991) H5879. Senator Ted Kennedy introduced S.B. 1523, parts of which in addition to dealing with NIH re-authorization, consider ways to modify the ban on fetal experimentation. The Senate passed the measure 83-14 on June 4, 1992. However, it passed the House by only 260-148, short of the two-thirds necessary to override a presidential veto. President Bush vetoed the measure on June 23, 1992 explaining he vetoed it "to prevent taxpayer funds from being used for research that many Americans find morally repugnant and because of its potential for promoting and legitimizing abortion." Adam Clymer, *Bush Vetoes Allowing U.S. To Fund Fetal-Tissue Study*, N.Y. TIMES, June 24, 199 at A13. Critics were quick to point out that politics had a lot to do with the veto. Robert Bazell, *Tissue Issue*, THE NEW REPUBLIC, June 29, 1992 at 10 (Bush offering millions of sick and desperate Americans an "enduring civic lesson"); *but see* Louis W. Sullivan, *Good Reason for the Fetal-Tissue Research Ban*, WASH. POST, Aug. 16, 1992 at C6 (Secretary Sullivan defends ban).

110. Sally Squires, *NIH Chief Backs Fetal Research Ban*, WASH. POST, April 16, 1991, at 5 (quoting Cong. Waxman).

ner. Pursuing the "New Biology" in such a manner requires adequate attention to the safety factor in all aspects of the experimentation.[111] The undesirable events of a Brave New World can be tempered only when knowledge is pursued with the purpose of establishing the truth and integrity of the question, issue, or process.[112] The vast potentials for advancing society and ridding it of a verisimilitude of its present ills is an obvious good which must be steadily pursued. Little sustaining harm can result from a reasonable pursuit of truth and knowledge; for, indeed, truth and knowledge are the basic interstices in any balancing test.[113] If actions are undertaken and performed with the goal of minimizing human suffering and maximizing the social good, then the noble integrity of evolution and genetic progress will be preserved.

So long as procreation continues to remain a central driving force in a marital relationship and the family the very core of a progressive society, efforts will be undertaken to expand the period of fecundity and combat infertility. Genetic planning and eugenic programming are more rational and humane alternatives to population regulation than death by famine and war.

Man must endeavor to execute his investigatory and manipulative or creative powers within the scientific laboratory with a rational purpose and in a spirit of humanism. Man should seek to minimize human suffering, thereby contributing to the social goal of allowing each member of society an equal opportunity to achieve their maximum output within the economic market place, and to maintain personal integrity and seek spiritual tranquility. Genetic engineering that contributes to the social good should be utilized fully. There can be no real doubt that genetic manipulation provides a perilous opportunity that may either threaten freedom or enhance it; depending upon the balance struck between its use for

111. Robert L. Sinsheimer, Paper *"The Dawn of Genetic Engineering,"* at a meeting of the Genetics Society of America, Chapel Hill, N.C., Aug. 17-20, 1975; 80 GENETICS 89 (1975) (abstract on file with HEALTH MATRIX), *see also* Sinsheimer *supra* note 106. *But see* Roy D. Meridith, Comments, *The Prospect of Private Unauthorized Eugenics and Ten Feet Tall Basketball Players: A Case of Legislative Oversight?*, 1 J. CONTEMP. HEALTH L. & POL'Y 155 (1985).

112. *See* George P. Smith, II, *Manipulating the Genetic Code: Jurisprudential Conundrums*, 64 GEO. L. J. 697 (1976). *See also* Karen Goodyear Krueger, Note, *Building a Better Bacterium: Genetic Engineering and the Patent Law After* Diamond v. Chakrabarty, 81 COLUM. L. REV. 159 (1981).

113. Joshua Lederberg, *Orthobiosis: The Perfection of Man*, *in* PLACE OF VALUE IN A WORLD OF FACTS 29 (Arne Tiselius & Sam Nilsson eds. 1980). *See generally* Bernard Ficarra, *Twentieth Century Indicators of Change in American Medical Practices for the 21st Century*, 6 J. CONTEMP. HEALTH L. & POL'Y 1 (1990).

individual need satisfaction and societal good.[114]

Restraining scientific inquiry, to my way of analysis, should be limited only to action considered to be unreasonable. Accordingly, an undertaking would be regarded as unreasonable when the long and short term costs of its effects would outweigh the enduring benefits that would derive from its study and implementation. Viewed, then, as being not only an aid to the tragedy of infertility in family planning, but as a tool for enhancing the health of a nation's citizens, vital scientific research must continue in the new, non-coital reproductive technologies and in efforts to engineer man's genetic weaknesses out of the line of inheritance. Healthier and genetically sound individuals have a much better opportunity for pursuing and achieving the "good life" and making a significant contribution to society's greater well being.

114. *See* Michael D. Kirby, *Bioethical Decisions and Opportunity Costs*, 2 J. CONTEMP. HEALTH L. & POL'Y 7 (1986); David Baltimore, *Limiting Science: A Biologist's Perspective*, DAEDALUS, Spring 1978, at 37; Leon Eisenberg, *The Social Imperatives of Medical Research*, 198 SCIENCE 1105 (1977). *See generally* GUSTAV JOSEPH VICTOR NOSSAL, HUMAN GENETIC INFORMATION: SCIENCE, LAW AND ETHICS (1990).